

REMARKS

This is in response to the Office Action of July 3, 2002. Claim 1 has been amended to incorporate specific nucleotide sequences and percent similarity from claim 2 and also to incorporate high stringency hybridization conditions from paragraph [0085]. See also paragraphs [0010]' and [0024]'. Claims 15 and 16 have been added directed to those nucleic acids individually. New claim 17 specifies the amino acid sequence encoded by the nucleotide sequences of claim 1. See paragraph [0077]. New claim 18 is limited to a portion of SEQ ID NO:1 that is not expressly disclosed in the Agostino reference. No new matter is introduced by this Amendment. Claims 1 and 3-18 are in the case, with claims 3-14 being withdrawn from consideration on their merits.

Formal rejections

Claims 1 and 2 were rejected under the second paragraph of 35 USC 112. The antecedent basis problem with the terminology "the expression" has been fixed. The terminology "a related cancer" has been removed. Claim 2 is canceled, and in claim 1, the high stringency conditions are recited in the claim. Accordingly, it is respectfully urged that this ground of rejection is obviated by the present Amendment.

Claims 1 and 2 were rejected under the first paragraph of 35 USC 112. Claim 1 was rejected because it relied only on a functional definition of the compounds being claimed. For the purposes of this ground of rejection, claim

1 as amended may be considered to correspond to original claim 2.

Claim 2 was rejected due to its inclusion of nucleotides meeting the functional criterion recited in claim 1 and having the defined degree of similarity to specified sequences OR being hybridizable to those sequences under LOW stringency conditions. Claim 1 as amended states that the sequences which are claimed in addition to SEQ ID NO:1 and SEQ ID NO:3 must (A) have the defined degree of similarity to those specified sequences, (B) AND being hybridizable to those sequences under HIGH stringency conditions and (C) meet the recited functional criterion. Those skilled in the art would have no difficulty in determining whether a given nucleotide sequence has at least about 60% similarity to SEQ ID NO:1 or to SEQ ID NO:3 after optimal alignment. Assuming it passed this test, one skilled in the art would have no difficulty in then determining whether that similar sequence is capable of hybridizing to SEQ ID NO:1 or to SEQ ID NO:3 under high stringency conditions defined as 0.1 x SSC buffer, 0.1% w/v SDS at a temperature of at least 65°C. If the 60% similar sequence does hybridize to a reference sequence under those high stringency conditions, a person skilled in the art could then determine by routine screening whether that sequence expresses an amount of mRNA that is differential or preferential in human hepatocellular carcinoma tissue or tissue from pancreatic adenocarcinoma relative to other tissue in said subject and/or in subjects not diagnosed with this condition.

Moreover, the present specification provides detailed and extensive disclosure relating to the "similarity" recited in the claim, starting in line 6 on page 22 of the specification and continuing through line 8 on page 26 of the specification.

It is respectfully submitted that the genus defined by the present claims is clearly delimited and fully supported, given the explanatory disclosure in the specification and the sophistication of those skilled in the relevant art.

Prior art rejections

Claim 1 was rejected under 35 USC 102(b) as being anticipated by US 5,866,329 (Demetriou). This ground of rejection is obviated by the incorporation of sequence-related recitations into claim 1.

Claims 1 and 2 were rejected under 35 USC 102(b) as being anticipated by WO 9845436 A2 (Agostino). While the reference sequence in Agostino provides a good match for the front 40% of Hcc-1, that is a far short of the 60% similarity required by claim 1 in its present form. Nothing in the prior art of record makes it obvious to modify that Agostino sequence in such a way as to create any of the sequences covered by the claims now before the Examiner. Accordingly, it is respectfully urged that this ground of rejection is obviated by the present Amendment.


Conclusion

It is respectfully requested that this application be passed to issue with claims 1 and 15-18. Applicants reserve the right to file divisional applications covering the inventions of claims 3-14.

If the Examiner has any questions concerning this application, he is requested to contact Richard Gallagher, Reg. No. 28,781, at (703) 205-8000 in the Washington, D.C. area.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,
BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 
Mark J. Nuell (Reg. No. 36,623)
P. O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

DRN/RG:gml

Attachment: Version with Markings to Show Changes Made

Marked up version of claim 1 showing changes:

1. (amended) An isolated nucleic acid comprising the nucleotide sequence of SEQ ID NO:1 or SEQ ID NO:3 or a nucleotide sequence, having at least about 60% similarity to the full length of SEQ ID NO:1 or SEQ ID NO:3, that hybridizes to SEQ ID NO:1 or SEQ ID NO:3 under conditions of 0.1 x SSC buffer, 0.1% w/v SDS, at a temperature of at least 65°C, [a sequence of nucleotides, the expression of which] wherein said nucleic acid expresses an amount of mRNA that is differential or preferential in human hepatocellular carcinoma tissue or tissue from pancreatic adenocarcinoma [a related cancer] relative to other tissue in said subject and/or in subjects not diagnosed with this condition.